REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the following remarks. Prior to the present amendment, claims 28-33 and 36-51 were pending, and claims 28-31, 36-39 and 44-47 were under consideration. By the present amendment, claims 32-33, 40-43, and 48-51 are canceled, and claims 28-31, 36-39 and 44-47 remain pending. Claims 36 and 44 are amended to more specifically recite one aspect of the invention. Support for the amendments may be found throughout the specification and claims as originally filed, and it is urged that the amendments do not constitute new matter. It should also be noted that the above amendments are not to be construed as acquiescence with regard to the Examiner's rejections and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application.

Second Supplemental Information Disclosure Statement

Applicants note that a Second Supplemental Information Disclosure Statement and the related Declaration of Emad S. Alnemri, Ph.D. are submitted with the present Amendment and Request for Continued Examination. The Second Supplemental Information Disclosure Statement lists a publication, Srinivasula *et al., J. Biol. Chem.* 275(46), 36152-36157 (2000), which was co-authored by Dr. Alnemri, the inventor of the presently claimed invention. As indicated in the accompanying Declaration, Dr. Alnemri was the sole inventor of the subject matter described in Srinivasula *et al.,* so this reference does not qualify as prior art under 35 U.S.C. § 102(a).

Objection to the Claims

Claims 44-47 stand objected to for allegedly being identical to claims 36-39.

Applicants respectfully traverse this basis of rejection and submit that the two groups of claims are not identical. Specifically, Applicants submit that claims 44-47 are drawn to an isolated Smac peptide or polypeptide **consisting of** an amino acid sequence of at least seven contiguous amino acid residues from at least residues 56-85 of SEQ ID NO:19, whereas

claims 36-39 are drawn to an isolated Smac peptide or polypeptide **comprising** an amino acid sequence of at least seven contiguous amino acid residues from at least residues 56-85 of SEQ DI NO:19. Accordingly, Applicants submit that the two groups of claims are clearly drawn to patentably distinct subject matter, and respectfully request that this basis of objection be reconsidered and withdrawn.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 36-39 and 44-47 stand rejected under 35 U.S.C. § 112, first paragraph, on the alleged basis that the instant specification is not sufficiently enabling for a Smac polypeptide comprising an amino acid sequence having at least seven contiguous amino acid residues from at least residues 56-85 of SEQ ID NO:19 and of which up to 183 contiguous amino acid residues can be from residues 56-239 of SEQ ID NO:19, wherein said Smac polypeptide or peptide is capable of binding to at least a portion of an Inhibitor of Apoptosis protein. Specifically, the Action alleges that the claims encompass Smac polypeptides that do not bind to a BIR domain or promote caspase activity. Furthermore, the Action asserts that it is unpredictable which of all possible claimed peptides and polypeptides containing seven contiguous amino acids of Smac residues 56-85 are capable of specifically binding to at least a portion of an Inhibitor of Apoptosis protein, in light of the specification disclosing that not any region of residues 56-139 is capable of promoting caspase activity.

Applicants respectfully traverse this basis of rejection and submit that the skilled artisan is enabled to practice the full scope of the claimed invention, in light of the teachings of the specification and the general knowledge attributable to one having ordinary skill in the art. Applicants submit that the claims are drawn to isolated Smac polypeptides comprising functional domains that bind to Inhibitor of Apoptosis (IAP) polypeptides, and further submit that the instant specification teaches specific amino acid residues associated with two IAP-binding domains first identified by Applicants and described in the instant specification. Accordingly, Applicants maintain the view that the skilled artisan could readily identify Smac peptides and polypeptides having the claimed characteristics. Applicants submit that screening Smac peptides and polypeptides for their ability to bind to IAP or a BIR domain thereof requires merely routine

procedures, which are widely known in the art and described in detail in the instant specification (*see, e.g.,* Examples 2 and 3).

However, to expedite prosecution of the instant application and without acquiescence to this basis of rejection, claims 36 and 44 have been amended to recite that the at least seven contiguous amino acid residues derived from at least residues 56-85 of SEQ ID NO:19 include residues 60-62, thus substantially reducing the number of claimed species. Applicants submit that support for this amendment is provided throughout the instant application, including, *e.g.,* on page 17, line 18 through page 18, line 2. Contrary to the Examiner's assertion, it is not only residues 56-62 of SEQ ID NO:19 that are capable of binding to a BIR domain and promoting caspase activity. As shown in Figure 10, while amino acids 56-62 of SEQ ID NO:19 are sufficient for binding to the BIR1/BIR2 or BIR3 domains, all seven of these amino acid residues are not required for binding to the BIR1/BIR2 domain, since binding to BIR1/BIR2 still occurred in the absence of residues 56-59, indicating that residues 60-62 are important for binding to the BIR1/BIR2 domain. Applicants respectfully submit that the presently claimed species are small in number, and the skilled artisan would have every reason to believe that the claimed species are operative, since they include the residues implicated in binding to the BIR1/BIR2 domain. Furthermore, Applicants submit that screening the limited number of claimed peptides and polypeptides for their ability to bind to IAP or a BIR domain thereof would require merely routine procedures, such as those described in Examples 2 and 3. Accordingly, Applicants submit that the skilled artisan is fully enabled to make and use the presently claimed invention and respectfully request reconsideration and withdrawal of this basis for rejection.

Rejection Under 35 U.S.C. § 102(e)

Claims 28-31, 36-39, 44-47 stand rejected under 35 U.S.C. § 102(e), as allegedly being anticipated by US 2002110851-A1. More specifically, the Action alleges that US 2002110851-A1 teaches a sequence of 84 amino acids in length, wherein said sequence comprises seven contiguous amino acids of residues 56-85 of SEQ ID NO:19. In addition, the

Action alleges that US 2002110851-A1 teaches a sequence of 29 amino acids in length, wherein said sequence comprises nine amino acids of residues 56-85 of SEQ ID NO:19.

Applicants respectfully traverse this basis of rejection and submit that US 2002110851-A1 is not prior art under 35 U.S.C. § 102(e). Applicants note that for a U.S. patent application to qualify as prior art under 35 U.S.C. § 102(e), it must be filed in the United States before invention by the Applicant. The U.S. filing date of US 2002110851-A1 is March 2, 2001, which occurs after the priority filing date of the instant application, which is August 24, 2000. Accordingly, US 2002110851-A1 does not qualify as prior art under 35 U.S.C. § 102(e), and Applicants respectfully request that this basis of rejection be withdrawn.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants respectfully submit that the claims remaining in the application are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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